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Providers' Internal Struggles to Understand and Interpret Ambiguous Regulatory Requirements Are Fair Game to the Government and Whistleblowers

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On June 1, 2023, the U.S. Supreme Court issued a highly-anticipated opinion available here, in *United States ex rel. Schutte v. SuperValu Inc.*,[1] which strengthened the False Claims Act (FCA),[2] and tilted the scales of power even more against providers.

The Court considered a growing defense to liability, which allowed a defendant to point to an "objectively reasonable interpretation" of an ambiguous regulatory requirement—even if it was not their subjective interpretation—in arguing they had not "knowingly" submitted a false claim. In a unanimous decision written by Justice Thomas, the Court held that evidence of a provider's contemporaneous subjective beliefs about the lawfulness of its conduct is always relevant to prove the FCA's scienter element, even when the provider is called to interpret an ambiguous regulatory requirement.

This article—written from the perspective of a former Assistant United States Attorney who prosecuted FCA cases for over 20 years—will explain the *Schutte* opinion and help providers understand what it means and what to do next.

A Reminder About False Claims Act Fundamentals

The FCA has long been the United States Department of Justice's (DOJ's) main enforcement tool against health care providers. It imposes civil liability on providers who "knowingly" submit false claims to government programs,[3] and its sharp teeth allow the government to collect treble damages and massive penalties from providers.[4]

Under the statute's qui tam provision,[5] a whistleblower—called a "relator"—can file suit on behalf of the government, and if the suit is successful at trial or by settlement, the relator is entitled to receive a percentage of the recovery as a reward for participation.[6] In addition, if the government elects not to intervene in the suit, the relator may pursue the case on the government's behalf, and if successful, the relator receives an even higher percentage of the recovery.[7] This reward structure has incentivized employees and competitors to become relators, and, buoyed by a powerful bar of relators' counsel, qui tam litigation has largely driven the United States' enforcement efforts under the FCA.

The FCA requires proof of four elements: falsity; scienter; materiality; and damages. The *Schutte* case involved the second element, scienter, which requires a showing that the provider "knowingly" filed a false claim, and may be satisfied in three different ways: (1) actual knowledge (a person is aware of information);[8] (2) deliberate ignorance (defendants who are aware of a substantial risk that their statements are false, but intentionally avoid taking steps to confirm the statements' truth or falsity);[9] or (3) reckless disregard (defendants who are conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway).[10]

To prove scienter, the government and relators regularly point to internal email or prior warnings as evidence that a provider knew or should have known a claim was false. While the government investigates allegations alleged in a qui tam complaint, prosecutors are statutorily authorized to issue Civil Investigative Demands[11] for the defendant's internal communications to obtain scienter evidence. If the government declines to intervene in the case, the relator must use traditional discovery tools to obtain the information. For that reason, a motion to dismiss is an essential defense.

The DOJ has recovered more than $70 billion since the FCA was amended in 1986.[12] Well over 700 FCA cases have been filed each year for the past 13 years and a high percentage of those cases have been qui tam cases.[13] In 2022, 948 new FCA cases were brought by both the government and qui tam relators, which was the most cases in any one year,[14] and 351 cases were resolved, which was the second highest number of recoveries in a single year.[15] Many qui tam cases remain under seal for years while the DOJ investigates the allegations and determines whether to intervene in the case. This means providers may not learn about cases filed against them until several years later.

The Background of the *Schutte* Litigation

The *Schutte* opinion emanated from consolidated appeals of two Seventh Circuit decisions in *United States ex rel. Schutte v. SuperValu Inc.*[16] and *United States ex rel. Proctor v. Safeway.*[17] These were qui tam suits brought against retail pharmacies owned by SuperValu and Safeway, which alleged the pharmacies submitted false claims to Medicare and Medicaid about their drug prices.[18] By regulation, Medicare and Medicaid cap the payment for drugs at a pharmacy's "usual and customary" price charged to the public. SuperValu and Safeway charged a retail price in some situations and offered a discounted price in other situations, so the term "usual and customary" was ambiguous. Pharmacy executives, the relators alleged, subjectively believed the discounted price should be reported as the "usual and customary" price, but the pharmacies nonetheless reported the higher retail price and submitted claims based on those prices.[19]

Relators filed qui tam suits under the FCA alleging the pharmacies reported higher prices to Medicare and Medicaid than what was usually and customarily charged to the public.[20] After an investigation, the government declined to intervene in the cases, so the relators pursued the claims independently. In both cases, the pharmacies filed motions for summary judgment. They asserted that the relator could not prove scienter because the definition of "usual and customary" was ambiguous, and an objectively reasonable interpretation of the regulation (although not understood by the pharmacies at the time) could have justified reporting and charging the retail price instead of the discounted price.[21] The pharmacies argued their subjective belief was irrelevant. The district courts agreed and granted summary judgment.

A split panel of the Seventh Circuit affirmed both cases.[22] The Seventh Circuit relied on the Supreme Court's decision in *Safeco Ins. Co. of Am. v. Burr*,[23] where the Supreme Court interpreted the Fair Credit Reporting Act and specifically, the term "willfully" as it is used in that statute.[24] Under the *Safeco* test, if a defendant articulates an objectively reasonable interpretation of an ambiguous requirement (even one that is post hoc or turns out to be erroneous), and no authoritative guidance had rendered the interpretation unreasonable, then it would be irrelevant that the defendant relied on a different interpretation of the requirement or subjectively believed the claim was false. Based on that test, the Seventh Circuit concluded the pharmacy executives' subjective belief that the discount price was "usual and customary" was irrelevant because an objectively reasonable interpretation would justify the claim.

According to the Seventh Circuit's opinions, when a requirement is ambiguous, "[a] defendant might suspect, believe, or intend to file a false claim, but it cannot know that its claim is false if the requirements for that claim are unknown."[25] The Seventh Circuit also questioned "how it would be possible for defendants to actually know that they submitted a false claim . . . if the requirements for that claim are unknown."[26] It reasoned the pharmacies could not act "knowingly" if an objectively reasonable interpretation of the

requirement to report the usual and customary price allowed a report of the retail price, and any internal deliberations showing a subjective concern about the issue was irrelevant. On that basis, the Seventh Circuit affirmed both decisions.[27]

The Seventh Circuit opinions were consistent with the opinions from every Circuit to construe the FCA's scienter standard, all of which have adopted the Supreme Court's decision in *Safeco*.[28] The Supreme Court granted the relators' Writs of Certiorari.

The Supreme Court Decision: Subjective Belief Is Always Relevant Scienter Evidence

The Supreme Court reversed the Seventh Circuit decisions, and ruled that a provider's subjective belief that a claim is false is always relevant to prove scienter under the FCA, even when an ambiguous regulatory requirement could be interpreted in a way that justified the claim.[29] The *Safeco* test does not apply to FCA cases; "[w]hat matters for an FCA case is whether the defendant knew the claim was false."[30]

The Court offered three hypotheticals to explain the scope of its decision. In the first hypothetical, the provider knowingly files a claim that is factually false: "If a law authorized payment of $100 for 'each' medical test, and a doctor knows that he did five tests but submits a claim for ten, then he has knowingly submitted a false claim."[31] The Supreme Court was not considering this situation, which did not require the provider to interpret an ambiguous requirement.

In the second hypothetical, "a law authorized payment for only 'customary' medical tests, [and] doctors [who are] confused when it came time for billing" misinterpret the term "customary," and through an honest mistake, submit a claim for tests that are not customary.[32] The Supreme Court was not considering this situation because the doctors subjectively believed their claims were true. The Court's third hypothetical was a spinoff of the second: instead of the doctors making an honest mistake about what tests were "customary," they "correctly understand whatever 'customary' meant in this context—and submit claims that were inaccurate anyway."[33] This third hypothetical was the Court's description of SuperValu and Safeway's conduct.

The Court clarified that scienter under the FCA refers to a defendant's knowledge and subjective beliefs—not to what an objectively reasonable person may have known or believed.[34] The focus must be on the provider's state of mind and subjective belief at the time the claim is filed, and post hoc rationalization is irrelevant to the scienter analysis. A facial ambiguity does not preclude a finding of scienter because it "does not preclude respondents from having learned their correct meaning – or, at least, becoming aware of a substantial likelihood of the terms' correct meaning."[35] The Court emphasized that the pharmacies did not make an honest mistake, and providers who filed claims they

subjectively believe are false could not escape liability by asserting the claim could be justified by an objectively reasonable interpretation of those legal requirements.[36]

The Court offered another hypothetical to show that a provider cannot rely on interpretations of ambiguous requirements that ignore contrary information and warnings:

> [C]onsider a hypothetical driver who sees a road sign that says "Drive Only Reasonable Speeds." That driver, without any more information, might have no way of knowing what speeds are reasonable and what speeds are too fast. But then assume that the same driver was informed earlier in the day by a police officer that speeds over 50 mph are unreasonable and then noticed that all the other cars around him are going only 48 mph. In that case, the driver might know that "Reasonable Speeds" are anything under 50 mph; or, at the least, he might be aware of an unjustifiably high risk that anything over 50 mph is unreasonable. Indeed, if the same police officer later pulled the driver over, we imagine that he would be hard pressed to argue that some other person might have understood the sign to allow driving at 80 mph.[37]

Converting this hypothetical driver to a health care provider, if a provider has no information that conflicts with its interpretation of an ambiguous requirement, and files a claim that later turns out to be false, the provider could prevail on the scienter element because it made an honest mistake. By contrast, if the provider receives guidance and warnings that should have led to a different interpretation, but ignores the information and still files a false claim, it is likely to lose on the scienter element. The latter was the case presented to the Supreme Court. The relators in the *Safeway* and *SuperValu* cases asserted[38] the pharmacies received notice from pharmacy benefit managers and state Medicaid agencies that the discounted drug price was the "usual and customary" price, which led them to conclude "if you [match a] price offer, that becomes your usual and customary [price] for that day."[39] The relators also asserted the pharmacy executives raised concerns about letting state agencies or pharmacy benefit managers learn about their discounted prices. In email, they described the discount program as a "stealthy approach" and directed employees to not "put any of this in writing to stores because our official policy is we do not match."[40] Despite all that, as alleged by the relators, the pharmacies reported and charged the higher retail price to Medicare and Medicaid. The Supreme Court did not equivocate in deciding this strong evidence of wrongdoing would satisfy the scienter element.

Key Takeaways for Providers

A provider faced with FCA allegations can no longer rely on an objectively reasonable interpretation of a substantive or procedural requirement to negate the scienter element. When a provider misinterprets or misapplies an ambiguous legal requirement and "knowingly" submits claims the government later considers inaccurate, the provider

cannot avoid liability by asserting an objectively reasonable interpretation that would have justified the claim. Instead, courts will look to the provider's subjective deliberations over the claim's accuracy, and the only relevant evidence will be what the provider subjectively knew or believed at the time it submitted the claim for reimbursement. Providers who have reason to think a claim violates regulatory requirements, even ambiguous ones, have no safe harbor. In other words, objectively reasonable post hoc interpretations are irrelevant when the provider knowingly submits a false claim.

The Supreme Court's opinion puts the burden on providers to "becom[e] aware of a substantial likelihood of [ambiguous] terms' correct meaning,"[41] so providers should renew efforts to seek clarification of any ambiguous requirement. Providers should not discount the notion that regulatory ambiguity is purposeful. The government has an incentive to include strategic ambiguity in the regulations and guidance because it can preserve future flexibility for the governmental payers. It certainly does not create a shield for the provider.

After the *Schutte* opinion, it may be more difficult for providers to obtain an early dismissal of FCA cases based on a lack of scienter. This affects providers in all states, and not just providers in the Seventh Circuit (Wisconsin, Illinois, and Indiana). Indeed, all of the Circuit Court opinions that permitted providers to assert the *Safeco* defense may soon be considered outdated law. After *Schutte*, if a complaint alleges, that a provider held a contemporaneous belief that a claim was inaccurate (with sufficient specificity to meet the standards set forth in Federal Rule of Civil Procedure 9(b)), a court will likely deny a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), and more cases will be sent to discovery. Only after enduring protracted and expensive discovery of documents and email, plus intrusive depositions, will providers have an opportunity to seek summary judgment, and trials are now more likely because scienter can be an issue of fact for the jury.

Scienter can be particularly difficult to prove in false certification cases, and providers should therefore be prepared for the government or relator to focus on internal email early and often. Remember that email and internal guidance can also be a useful source of evidence against scienter—that the provider believed the claim was accurate—and such evidence can support a strong defense. When appropriate, consider documenting contemporaneous beliefs that claims to government payers are accurate, especially when relying on legal advice or consultants.

The best response to the *Schutte* opinion is to reinforce efforts to clarify any ambiguous requirements and continue avoiding all false claims. A robust and effective compliance program can be the key to avoiding FCA liability. When making compliance decisions, it is a good idea to have legal counsel on speed dial. That has not changed.

About the Author

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Special thanks to Abby Dreiling for her contribution to this article. Ms. Dreiling a law student at the University of Richmond School of Law and a summer associate at Hancock Daniel.

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[1] 598 U.S. ___, 2023 U.S. LEXIS 2300 (June 1, 2023).

[2] 31 U.S.C. § 3729 *et seq*.

[3] § 3729(a)(1)(A).

[4] § 3729(a).

[5] § 3730(b).

[6] § 3730(d)(1).

[7] § 3730(d)(2).

[8] § 3729(b)(1)(A)(i); *Schutte,* 2023 Lexis 2300 at *18.

[9] § 3729(b)(1)(A)(ii); *Schutte,* 2023 Lexis 2300 at *18.

[10] § 3729(b)(1)(A)(iii); *Schutte*, 2023 Lexis 2300 at *18.

[11] § 3733.

[12] The DOJ Fraud Recovery Statistics are available here.

[13] DOJ Office of Public Affairs, Fraud Statistics – Overview (February 7, 2023).

[14] *Id.*

[15] *Id*.

[16] 9 F.4th 455 (7th Cir. 2021).

[17] 30 F.4th 649 (7th Cir. 2022).

[18] *Schutte*, 9 F.4th at 459; *Proctor*, 30 F.4th at 657.

[19] *Schutte,* 9 F.4th at 459; *Proctor,* 30 F.4th at 655-56.

[20] *Id.*

[21] *Schutte*, 9 F.4th at 462; *Proctor*, 30 F.4th at 657.

[22] *Schutte*, 9 F.4th at 472; *Proctor*, 30 F.4th at 662.

[23] 551 U.S. 47 (2021).

[24] *Id.* at 52.

[25] *Schutte*, 9 F.4th at 468.

[26] *Id.*

[27] *Id.*

[28] *See e.g., United States v. Allergan*, 746 F. App'x 101, 106 (3rd Cir. 2018) (summary judgment affirmed because defendant's claims, while false, were consistent with an objectively reasonable interpretation of an ambiguous requirement to report the Average Manufacturer's Price); *United States ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017) (evidence that defendant knew it did not comply with ambiguous requirement was irrelevant because defendant's interpretation was objectively reasonable at the time); *United States ex rel. Sheldon v. Allergan Sales, LLC*, 49 F.4th 873, at *1 (4th Cir. 2022) (*en banc*), *aff'g* 499 F. Supp. 3d 184, 207 (D. Md. 2020) (without opinion) ("because Forest's interpretation is objectively reasonable, Relator cannot plausibly allege that Forest acted with the requisite scienter unless he can demonstrate that defendant had been warned about its interpretation."); *United States ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC*, 833 F.3d 874, 879-80 (8th Cir. 2016) (provider's interpretation was objectively reasonable, so knowing submission of a false claim could not be shown); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 284, 420 U.S. App. D.C. 176 (D.C. Cir. 2015) (FCA's objective knowledge standard did not permit a jury to find that the corporation knowingly made a false claim); *United States ex rel. Olhausen v. Arriva Med. LL*, 2022 U.S. App. LEXIS 10989, at *2 (11th Cir. Apr. 22, 2022) (plaintiff cannot show defendants had requisite

scienter because defendant articulated an objectively reasonable interpretation of the Medicare rules).

[29] *Schutte*, 2023 U.S. LEXIS 2300, *16.

[30] *Id.* at *7.

[31] *Id.* *6.

[32] *Id.*

[33] *Id.*

[34] *Id.* at *17-18.

[35] *Id.* at *20-21.

[36] *Id.* at *20.

[37] *Id.* at *21.

[38] Because the appeals derived from the District Courts' grant of summary judgment in both cases, the Supreme Court was required to construe the facts in the light most favorable to the relators. On remand, the evidence could be more favorable to the pharmacies.

[39] *Schutte*, 2023 U.S. LEXIS 2300, *12.

[40] *Id*.

[41] *Id.* at *21.